BEST AVAILABLE COPY

TABLE OF CONTENTS

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iv

INTEREST OF *AMICI CURIAE* 1

SUMMARY OF ARGUMENT 3

ARGUMENT 5

I. SCIENTIFIC EXPERT TESTIMONY POSES SPECIAL CHALLENGES FOR COURTS AND NON-SCIENTIST FACT-FINDERS 5

II. SCIENTISTS USE ESTABLISHED CRITERIA AND INSTITUTIONAL MECHANISMS TO EVALUATE SCIENTIFIC CLAIMS 7

A. Science Represents An Ongoing Process Of Inquiry To Explain Natural Phenomena 7

B. In Pursuing Their Own Research, Scientists Routinely Evaluate The Work Of Colleagues 10

C. Institutional Checks Exist To Assist In Evaluating The Validity Of Scientific Research 13

III. COURTS SHOULD EXCLUDE EXPERT TESTIMONY DERIVED FROM THEORIES, REASONING, OR METHODOLOGIES THAT DO NOT CONFORM TO SCIENTIFIC CRITERIA AND STANDARDS 19

A. In Evaluating Disputed Scientific Evidence Courts Should Consider The Same Factors That Scientists Consider . . 19

B. Courts Should Take Into Account The Results Of Peer Review In Assessing The Validity And Reliability Of Scientific Evidence 21

C. Courts Should Determine The Competence Of Scientific Evidence As A Threshold Matter 22

D. Threshold Determinations Concerning The Admissibility Of Scientific Evidence Are Consistent With The Federal Rules Of Evidence 24

CONCLUSION 28

TABLE OF AUTHORITIES

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aff'd, 870 F.2d 642 (Fed. Cir. 1989) 15

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cert. denied, 479 U.S. 950 (1986) 23

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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT, *et al.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF FOR THE AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE AND THE NATIONAL ACADEMY OF SCIENCES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF *AMICI CURIAE*[1/]

The American Association for the Advancement of Science ("AAAS") is a non-profit scientific society that, among other objectives, seeks to increase public understanding and appreciation of the importance and promise of science in advancing human progress. Founded in 1848, the AAAS is now the world's largest general scientific organization. It has nearly 300 affiliate organizations, and more than 134,000 scientists, engineers, educators, policy

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1/ This brief is filed with the permission of the parties. Written consents have been provided to the Clerk of this Court.

makers, and interested citizens among its members. *Science*, the official journal of the AAAS since the turn of the century, is one of the world's most frequently cited scientific journals.

The National Academy of Sciences ("NAS") is one of the world's most prestigious scientific organizations. It is a private, self-perpetuating organization, and selection for membership is a significant honor. Its congressional charter, which was signed into law by President Lincoln, provides that the Academy "shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art . . . ." 36 U.S.C. § 253 (1988). Working through the National Research Council, the Academy examines scientific and technological questions of national importance, typically referred to it by Congress or the Executive Branch.

Amici have had a continuing involvement in the intersection of science and law.[2/] *Amici* file this brief because of their interest in assuring that the courts avoid reliance on putatively scientific evidence that does not in fact reflect the application of scientific principles. Such evidence can lead to incorrect decisions and can serve to discredit the contributions of science. Scientists have an interest in

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[2/] The Academy, for example, recently issued a detailed report dicussing the possible forensic applications of DNA typing. *See* National Research Council, *DNA Technology in Forensic Science* (1992). This report devotes an entire chapter to issues concerning the admissibility of DNA evidence in criminal and civil proceedings.

assuring that the fruits of their labors are understood and properly used by others in society.

This case presents an important opportunity to clarify how courts should evaluate and screen scientific evidence. Petitioners assert that the authority of the federal courts to exclude such evidence should be narrowly constrained. *Amici* disagree. In evaluating scientific evidence, courts should consider the same factors that scientists themselves employ to assess the validity and reliability of scientific assertions.

Amici have filed this brief to explain those factors that are particularly relevant to the case pending before the Court and the way in which scientists apply them in the day-to-day practice of their profession. Although *amici* do not comment directly on the available evidence concerning the alleged teratogenicity of Bendectin, they support Respondent's position that courts have the authority and the responsibility to exclude expert testimony that is based upon unreliable or misapplied methodologies.

SUMMARY OF ARGUMENT

The courts below correctly recognized the difficulties that attend the consideration and use of scientific evidence in the courtroom. Such evidence often may be difficult to assess and yet may be of determinative significance. To avoid outcomes that are at odds with reality, courts must exercise special care to assure that such evidence is based on valid and reliable scientific methodologies.

Courts can best accomplish this difficult task by applying the same criteria that scientists themselves regularly apply in picking and choosing the theories, explanations, and methods upon which they build their own work. Although the details of science may be remote from common experience, judges can understand the fundamental characteristics that separate good science from bad. Courts should also consider the institutional mechanisms, namely the different forms of peer review, that have been developed to assure that scientists conduct their work in accordance with appropriate scientific criteria.

When faced with disputes about expert scientific testimony, judges should make full use of the scientific community's criteria and quality-control mechanisms. To be admissible, scientific evidence should conform to scientific standards and should be based on methods that are generally accepted by the scientific community as valid and reliable. Threshold determinations concerning the admissibility of scientific evidence are necessary to ensure accurate decisions and to avoid unnecessary expenditures of judicial resources on collateral issues. Judicial control of this sort is fully in keeping with the Federal Rules of Evidence.

ARGUMENT

I. SCIENTIFIC EXPERT TESTIMONY POSES SPECIAL CHALLENGES FOR COURTS AND NON-SCIENTIST FACT-FINDERS.

Scientific evidence can present special problems in litigation. It is often couched in peculiar terms, may derive from complicated scientific principles and seemingly unusual methods of proof, and sometimes addresses issues of fact that are very different from those confronted in everyday life.[3/] Because fact-finders may perceive expert scientific evidence as carrying a special stamp of certainty and authority, they sometimes give particular credence to scientific experts.[4/]

3/ *See* Loevinger, *Standards of Proof in Science and Law*, 32 JURIMETRICS J. 323, 333 (1992) ("[T]he basic techniques of science are measuring and counting, and the language that best expresses the data gathered by these techniques is the language of numbers. . . . [S]cientific standards of proof are expressed numerically, stating degrees of probability or confidence, while legal standards of proof are categorical and expressed entirely in verbal terms." (footnote omitted)); Elliott, *Toward Incentive Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U.L. REV. 487, 487-88 n.3 (1989) ("By their very nature, disciplines such as toxicology rely on specialized techniques that run counter to a lay person's intuitions." (citation omitted)).

4/ *See* United States v. Brown, 557 F.2d 541, 556 (6th Cir. 1977) ("Because of its apparent objectivity, an opinion that claims a scientific basis is apt to carry undue weight with the trier of fact."); United States v. Addison, 498 F.2d 741, 744 (D.C. Cir. 1974) ("scientific proof may in some instances assume a posture of mystic infallibility in the eyes of a jury of laymen").

Scientific evidence may also have particular importance in certain types of litigation because it can illuminate crucial issues that otherwise would remain in darkness. For example, in a toxic tort case, science can provide unique insights into the likelihood that exposure to a certain chemical caused the injury at issue. Such testimony may provide the sole foundation for determining whether a plaintiff can satisfy a causation requirement.

Finally, scientific evidence presents unique challenges because it may not be able to provide definitive pronouncements. Scientists must often be satisfied with probabilistic statements made in the context of particular theoretical assumptions or experimental methodologies.[3/] The proper consideration of scientific evidence requires sensitivity to those assumptions and methodologies and to the reality that scientific knowledge is often evolving and changing.

The unique persuasive power of scientific evidence -- and its inherent limitations -- requires that courts engage in special efforts to ensure that scientific evidence is valid and reliable before it is admitted. In performing that task, courts can look to the same criteria that scientists themselves use to evaluate scientific claims.

3/ *See* Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substances Litigation*, 73 CORN. L. REV. 469, 478-83 (1988).

II. SCIENTISTS USE ESTABLISHED CRITERIA AND INSTITUTIONAL MECHANISMS TO EVALUATE SCIENTIFIC CLAIMS.

The scientific community has a special interest in encouraging innovative thinking while simultaneously ensuring that new ideas are subjected to rigorous review. On the one hand, science is a creative process in which advances occur only if researchers develop and test innovative ideas. Indeed, the scientific community reserves its highest honors for those individuals who have taken chances on novel approaches to problems. On the other hand, because science is a cumulative subject in which each scientist must build on the work of others, the scientific community also places great emphasis on weeding out false ideas. Accordingly, creativity is tempered by the need for rigorous testing and review of new approaches.

Individual scientists must be able to identify "good" science in pursuing their own research. The fundamental criteria they apply in doing so are neither arcane nor remote, and can be understood by educated and informed lay persons. Similarly, judges can understand and rely on the institutional processes that science has developed to help evaluate scientific assertions.

A. Science Represents An Ongoing Process Of Inquiry To Explain Natural Phenomena.

Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a *process* for proposing and refining theoretical explanations about the world that are

subject to further testing and refinement.[6] Scientists accept a scientific explanation for an event when that explanation is corroborated by experiments using accepted methodologies and when it is consistent with other accepted explanations. Corroboration is generally based on the correct prediction of observed events or results. In some fields, such as cosmology, consistency with general theory may be especially important. In other fields, such as biochemistry, experimentation provides the primary means for evaluating hypotheses. In still other fields, such as astronomy, observation rather than experimentation is relied upon to corroborate theoretical predictions. At its core, however, science is a process of evaluating testable propositions to assure conformance with observable reality.

Although there is no simple recipe for the conduct of scientific work, science does proceed through a series of interrelated steps centered on the generation and testing of hypotheses. Hypotheses are educated guesses about a particular phenomenon or event. An hypothesis is tested for its internal consistency, explanatory value, and accuracy in predicting observed results.[7] Applying these basic requirements, one would reject an hypothesis which is self-contradictory, tautological, or inaccurate in predicting outcomes.

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[6] Loevinger, *supra* note 3, at 328 ("[S]cience is not so much a body of knowledge as an endless search for universal laws and a more inclusive coherent system of hypotheses.").

[7] *See* Ayala & Black, *The Nature of Science: A Primer for the Legal Consumer of Scientific Information*, 1 SCI. & COURTS 1 (Winter 1993).

Science thus involves far more than mere observation. Valid science must also explain and clarify relationships. The key to valid science is a convergence of well reasoned explanation with supporting observations or experimental results. No discrete set of experiments can establish that an hypothesis is true in all situations. Rather, scientists conduct rigorous experimental testing in an attempt to falsify hypotheses. An hypothesis is accepted as generally valid to the extent that it has survived repeated attempts at falsification. "*Observation*, *reason*, and *experiment* make up what we call the *scientific method*."[8]

In some instances, corroboration and consistency with existing theories may elevate an hypothesis to the status of a theory, which may eventually mature into a scientific law. For example, thermodynamics and Newton's laws of motion have achieved the status of laws, reflecting the high level of confidence that scientists place in the predictions that these laws provide.[9] It is only through a process of continual challenge that confidence in the validity of a scientific proposition may emerge.

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[8] R. FEYNMAN, R. LEIGHTON & M. SANDS, THE FEYNMAN LECTURES ON PHYSICS 2-1 (1963) (emphasis in original).

[9] Important observations can quickly become part of accepted scientific knowledge. The double-helix model of DNA first proposed by James Watson and Francis Crick in 1953 became accepted by the scientific community and was used as the basis for all research in molecular biology after the hypothesis was corroborated by critical experiments undertaken in 1958. Meselson & Stahl, *The Replication of DNA in* Escherichia coli, 44 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES (U.S.A.) 671, 681-82 (1958).

B. In Pursuing Their Own Research, Scientists Routinely Evaluate The Work Of Colleagues.

In light of the immensity of contemporary scientific knowledge, no scientist could conceivably corroborate the validity of all of the theories, methods, and results on which he or she must rely in research. As a result, each scientist must decide whether to accept particular hypotheses or research data as the foundation for further work.[10/] This process involves the weighing of a variety of factors to ensure that the underlying work is reliable.

Scientists evaluate whether an hypothesis has been rigorously tested and whether the data have been derived using methods or protocols deemed acceptable in the field. In conducting such an evaluation, scientists consider the credentials of the proponent of a particular hypothesis or of the source of the data, including whether the research is in a field in which the proponent's education or experience indicates expertise. Reliance on an hypothesis generated by another might also depend on whether the experimental evidence is sufficient to reject reasonable alternative hypotheses and is consistent with existing scientific theories pertaining to that field. Similarly, reliance on another's research data might turn on an evaluation of the consistency of the results with data gathered by several others in the relevant field.

These considerations do not, of course, exhaust the range of criteria that scientists use in evaluating scientific

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10/ *See* Black, *A Unified Theory of Scientific Evidence*, 56 FORD. L. REV. 595, 620-26 (1988).

work, but they do reflect the basic concern for probing the foundations of research results to assess conformance with scientific standards. Scientists would, for instance, typically not be inclined to rely on an hypothesis based on nothing more than reinterpretations of existing data if the new hypothesis is uniformly inconsistent with the results of other previously published research. Because experimentation is itself subject to error, scientists also require replication of tests, particularly before rejecting important or previously corroborated hypotheses.

There is an obvious danger that research results generated solely for litigation may be skewed. "A scientist who has a formed opinion as to the answer he is going to find before he even begins his research may be less objective than he needs to be in order to produce reliable scientific results."[11/] Indeed, experts who testify about research results that have not been submitted for scientific scrutiny, despite ample opportunity for publication, may not be truly acting in their capacity as scientists. One court has observed that "many such able persons present studies and express opinions that they might not be willing to express in an article submitted to a refereed journal of their discipline or in other contexts subject to peer review."[12/]

11/ Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985); *see* Feinstein, *Scientific Standards in Epidemiological Studies of the Menace of Daily Life*, 242 SCIENCE 1257 (1988) (emphasizing importance of stipulating a research hypothesis in advance of data collection).

12/ *In re* Air Crash Disaster at New Orleans, 795 F.2d 1230, 1234 (5th Cir. 1986) ("That a person spends substantially all of his time (continued...)

Of course, not every scientific conclusion is of an importance that warrants publication or even detailed peer scrutiny. Some matters may have a significance in litigation that far exceeds their scientific interest. For example, the hydrological evaluation of a chemical waste site might have enormous import in litigation, but, unless some previously undetected phenomena were encountered, it would likely be of little general scientific interest. The test applied by scientists in evaluating such results would turn on whether their proponent has consistently adhered to the kind of reasoning that constitutes science, and has made plausible assumptions and used an accepted methodology in reaching his or her conclusions.[12]

On the other hand, research results that are advanced solely in litigation and that conflict with existing learning should be viewed with caution. Such information, if correct, is of scientific significance and ordinarily would warrant publication. Experts who propose to do nothing more with

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[12](...continued)
consulting with attorneys and testifying is not a disqualification. But experts whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an 'expert.'"); *see also* Johnston v. United States, 597 F. Supp. 374, 414, 415 (D. Kan. 1984) ("[T]hese witnesses say and conclude things which, in the Court's view, they would not dare report in a peer-reviewed format."); Brent, *The Irresponsible Expert Witness: A Failure of Biomedical Graduate Education and Professional Accountability*, 70 PEDIATRICS 754, 755 (1982).

[13] *See* Kezsbom & Goldman, *The Boundaries of Groundwater Modeling Under the Law: Standards for Excluding Speculative Expert Testimony*, 27 TORT & INSUR. L.J. 109 (1991).

seemingly remarkable discoveries than submit them to judges and juries are not acting in a manner characteristic of scientists.[14] Presentation of the information to the scientific community in some fashion is the sole means by which the new work can become part of the body of scientific knowledge.

C. Institutional Checks Exist To Assist In Evaluating The Validity Of Scientific Research.

A new theory or explanation must generally survive a period of testing, review, and refinement before achieving scientific acceptance. This process does not merely reflect the scientific method; it is the scientific method.[15] Peer review, in its broadest sense, represents the scientific community's effort to police itself and to assure a certain minimum level of quality so that scientists and others can rely on the results of reported scientific research. Moreover,

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[14] *See Perry*, 755 F.2d at 892 ("[T]he examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine."). The same complaint can be levied against scientists who attempt to avoid peer review by presenting their findings to the lay media, as happened a few years ago when Utah researchers announced at a press conference that they had discovered "cold fusion." The resulting controversy illustrates the importance of conducting confirmatory experiments and encouraging careful scrutiny by colleagues. *See Cold-Fusion Claim is Faulted On Ethics as Well as Science*, N.Y. Times, March 17, 1991, at 1; *Cold Fusion Still Escapes Usual Checks of Science*, N.Y. Times, Oct. 30, 1990, at C1, C8.

[15] *See* J. ZIMAN, RELIABLE KNOWLEDGE: AN EXPLORATION OF THE GROUNDS FOR BELIEF IN SCIENCE 130-32 (1978); Relman & Angell, *How Good is Peer Review?*, 321 NEW ENGL. J. MED. 827, 828 (1989).

peer review contributes to the advancement of science not merely through the screening of scientific work, but also by helping proponents of new hypotheses to improve their research and interpretations.

This scientific scrutiny takes place in a variety of contexts. As one court has explained:

> Scientific truth and the acceptability of scientific procedure are not normally established by public opinion polls. The scientific community uses entirely different methods for such purposes (*e.g.*, articles in learned journals, seminars, acceptance at institutions of higher learning). . . . [These procedures] are time-honored precisely because scientific truth generally requires this kind of maturation of a consensus.[16]

Informal peer review can occur when scientists discuss their work with one another at the laboratory bench, during conversations and seminars, and at scientific meetings. Formal peer review is generally an intrinsic part of the scientific publication process and the process by which funds are allocated for the conduct of research. At a minimum, any claim that would significantly add to or change the body of scientific knowledge is regarded skeptically until it has been subject to some form of peer scrutiny.

Peer review of manuscripts submitted to scientific journals is a fundamental part of scientific practice.

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[16] Dowd v. Calabrese, 585 F. Supp. 430, 432 (D.D.C. 1984).

Typically, the editors of a journal call on the assistance of outside experts to "referee" manuscripts -- that is, to provide advice on their suitability for publication.[17] Referees enlisted to peer review manuscripts do not merely provide recommendations as to whether a study should be published. Instead, their primary job is to provide constructive criticism so that a manuscript or the underlying research can be improved.

Because scientific work often depends upon complex underlying assumptions and choices of methodology, probing and careful review by other scientists is indispensable. Dr. William W. Havens, Jr., Professor Emeritus of Applied Physics at Columbia University, has explained that "[s]cience is a cumulative enterprise in which each scientist builds on the work of others. Because of the enormous expense that would be associated with reproducing the results of others, a scientist must rely to a significant extent on the validity of reported results."[18] Publication in peer-reviewed journals

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[17] *See* Solarex Corp. v. Arco Solar, Inc., 121 F.R.D. 163, 164, 167-68 (E.D.N.Y. 1988) (use of qualified editors and outside referees provides an important quality-control mechanism for scientific publications), *aff'd*, 870 F.2d 642 (Fed. Cir. 1989); Lock & Smith, *What Do Peer Reviewers Do?*, 263 J.A.M.A. 1341 (1990).

[18] Affidavit quoted in *Solarex*, 121 F.R.D. at 171. As a result, "the peer review function performed by independent referees for editors of scholarly journals contributes to the advancement of science by helping to assure that 'faulty, incomplete or misleading results are not published.'" *Solarex*, 121 F.R.D. at 171; *see also Policy of AMA Journals Regarding Release of Information to the Public*, 265 J.A.M.A. 400 (1991) ("All concerned want medical information to be as accurate as

(continued...)

is one of the most important mechanisms for screening, disseminating, and preserving new research results. Publication also engages scientists in a public dialogue about new research, providing an opportunity for clarification and refinement.

The use of peer review in the publication process has its critics, and their complaints must be given due consideration.[19] For example, some have argued that peer review stifles innovation,[20] and even its defenders concede that the process cannot always ferret out scientific fraud,[21] or provide a guarantee of scientific validity.[22] Even the most

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[18](...continued)
possible. Medical editors rely on rigorous peer review to evaluate such accuracy prior to accepting papers . . . .").

[19] The editors of the *Journal of the American Medical Association* devoted an entire issue to articles addressing problems surrounding peer review in the publication process. *Guarding the Guardians: Research on Editorial Peer Review*, 263 J.A.M.A. 1306-1456 (March 9, 1990).

[20] *See* Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 J.A.M.A. 1438 (1990).

[21] *See* Rennie, *Editors and Authors*, 261 J.A.M.A. 2543, 2544 (1989) ("[A]lthough it may work well when the questions being asked of it are the questions of science, peer review has proved to be of little use in determining if the information provided in the first place is either complete or honest."); *Bill Would Set Fraud Guidelines for Scientific Publications*, 242 SCIENCE 187 (1988).

[22] *See* Relman & Angell, *supra* note 15, at 828 ("[A]lthough peer review can screen out work that is clearly invalid and greatly improve the chances that published work is valid, it cannot guarantee scientific validity.").

vocal critics of the peer review system do not, however, recommend that it be dismantled.[23] Indeed, in response to some of these complaints, scientific organizations have made efforts to improve the integrity of the process. Although by no means perfect, peer review in the publication process is relied upon by the scientific community as the best means for identifying valid scientific research and conclusions.[24]

Federal agencies often rely on peer-review processes to allocate scarce federal research dollars to those projects that hold the greatest scientific promise.[25] Federal regulatory agencies have also placed increasing reliance on the expertise of outside scientists through the establishment of special advisory committees or some other form of peer review. The Food and Drug Administration ("FDA") and the Environmental Protection Agency ("EPA") have been at the forefront of this trend. Some of these expert advisory

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[23] *See* Horrobin, *supra* note 20; Knoll, *The Communities of Scientists and Journal Peer Review*, 263 J.A.M.A. 1330 (1990).

[24] *See* Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 NW. U. L. REV. 643, 694-95 n.210 (1992) (discussing flaws identified with peer review system, but concluding that courts do not have any more refined mechanism for determining the validity of scientific studies); Klein, *Expert Testimony in Pharmaceutical Product Liability Actions*, 45 FOOD DRUG COSM. L.J. 393, 427 (1990).

[25] *See, e.g.*, 42 U.S.C. § 289a (1988) (requiring peer review of NIH grant applications); 42 C.F.R. § 52h.7(a) (1991) (NIH regulations); 45 C.F.R. Pt. 602 (1991) (National Science Foundation regulations).

committees have been established by statute,[26/] while a great many others are agency creations.[27/] Indeed, in some instances, Congress has mandated the use of peer review for certain agency actions.[28/]

In sum, peer review provides courts with many sources of information that may be useful in evaluating scientific evidence. Courts should make full use of the considered opinions of the scientific community when attempting to assess such evidence.

[26/] *See, e.g.*, 7 U.S.C. § 136w(d) (1988) (EPA's Scientific Advisory Panel, which is concerned with pesticide registrations); 21 U.S.C. § 360c(b) (1988 & 1992 Supp.) (FDA's medical device classification panels); 21 U.S.C. § 376(b)(5) (1988) (FDA's color additive advisory committees).

[27/] *See, e.g.*, 21 C.F.R. § 14.100 (1992) (listing FDA's numerous standing advisory committees). The Administrative Conference has endorsed the use of such advisory committees because "[t]he quality and legitimacy of . . . agency decisions can be improved by counseling with eminent scientific experts outside the agency." 1 C.F.R. § 310.11 (1992). Courts reviewing agency actions based on complicated scientific evidence have echoed this sentiment. *See* Asbestos Information Ass'n v. Occupational Health & Safety Admin., 727 F.2d 415, 421 & n.15 (5th Cir. 1984).

[28/] *See, e.g.*, 7 U.S.C. § 136w(e) (1988) (requiring peer review of major scientific studies concerning pesticides conducted by or with the EPA); 42 U.S.C. § 9604(i)(13) (1988) (Superfund provision requiring that "[a]ll studies and results of research conducted under this subsection (other than health assessments) shall be reported or adopted only after appropriate peer review"); 42 U.S.C. § 1396r-8(k)(6) (1992 Supp.) (authorizing Medicaid reimbursement for any use of a prescription drug that "appears in peer-reviewed medical literature" even if FDA has not specifically approved that use of the drug).

III. COURTS SHOULD EXCLUDE EXPERT TESTIMONY DERIVED FROM THEORIES, REASONING, OR METHODOLOGIES THAT DO NOT CONFORM TO SCIENTIFIC CRITERIA AND STANDARDS.

Courts should admit scientific evidence only if it reasonably conforms to scientific standards and is derived from methods that are generally accepted as valid and reliable. Such a test for admissibility would incorporate the factors, including the results of peer review, that scientists consider in evaluating each other's work.

A. In Evaluating Disputed Scientific Evidence Courts Should Consider The Same Factors That Scientists Consider.

Although many judges may lack extensive scientific training, they can understand the basic characteristics that separate valid science from mere speculation. The scientific commitment to providing explanations that are supported by observational and experimental evidence should apply when an expert testifies in court, just as it does when he or she reports results to other scientists. Only in this way can prejudicial speculation be distinguished from valid science. Indeed, the basic logic of science does not differ from the logic of the law. In both, understandable explanations must connect evidence to conclusions about the evidence.[29/]

Courts can and should decide disputes about scientific evidence based on an understanding of the overarching

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[29/] *See* Loevinger, *supra* note 3, at 328 & n.26.

principles that govern the way good science is conducted. For example, a physician should not be allowed to claim that a substance caused someone to develop a common illness simply because another of his patients developed a similar illness after years of exposure to the same substance. Similarly, an expert should not be permitted to assert that a substance is a human carcinogen on the basis of nothing more than inconclusive animal testing. Although these observations may provide an interesting foundation from which to generate hypotheses about causation that warrant careful exploration, no scientist would accept the offered conclusions, without more, as scientifically valid. Courts likewise should have no trouble in recognizing the shortcomings of such evidence if they assess these assertions against the basic criteria of scientific validity.

The characteristics of valid science are neither remote nor arcane, and a judge should not hesitate to consider them in evaluating disputed scientific evidence. Although judges often will be unable to bring the same expertise to such a task as a specially trained scientist, they are in a position to determine if scientific evidence possesses the characteristics of valid science and to consider the same factors that busy scientists use to evaluate research performed by other scientists. To the extent that a judge feels a need for additional information or guidance in making determinations of scientific validity, Rule 706 of the Federal Rules of Evidence authorizes the appointment by the court of experts to assist in such matters.

B. Courts Should Take Into Account The Results Of Peer Review In Assessing The Validity And Reliability Of Scientific Evidence.

In evaluating the admissibility of scientific evidence, courts should consider not only the characteristics of valid science, but also the extent to which a claim has been subjected to peer review by other scientists. *Amici* do not assert that peer review or publication is either a necessary or a sufficient condition for establishing the validity of a scientific claim. Some published research later may prove to be invalid, and research that has been rejected for publication may, in some situations, turn out to be perfectly valid. For purposes of guiding courts, however, survival of peer-review scrutiny provides a useful indicator of the judgments of other scientists about the validity of new hypotheses. Unreviewed research has not yet survived the screening function that scientists customarily demand in the dissemination of scientific results.

The need for skepticism of unreviewed research is especially important when an expert expresses disagreement with a substantial body of published research, offering instead his or her own unpublished conclusions. No court should permit an expert to testify in a paternity suit that he believes, on the basis of unreported experiments demonstrating the importance of environmental influences, that the theory of heredity offers no guidance for establishing the identity of a child's father. Nor should a judge countenance the introduction of testimony in a traffic-accident case that disputes the application of Newton's laws of motion, no matter how sincere the expert's claim. Although these

situations represent extreme cases, it is clear that a court must have the power to reject such testimony. Even if these experts have stumbled onto something truly remarkable, such breakthroughs should not be resolved by a court of law in the first instance.

C. Courts Should Determine The Competence Of Scientific Evidence As A Threshold Matter.

Determinations concerning the admissibility of expert testimony based on scientific evidence should be made by a judge in advance of trial. Such judicial control is explicitly called for under Rule 104(a) of the Federal Rules of Evidence,[20] and threshold admissibility determinations by a judge serve several important functions, including simplification of issues at trial (thereby increasing the speed of trial), improvement in the consistency and predictability of results, and clarification of the issues for purposes of appeal. Indeed, it is precisely because a judge can evaluate the evidence in a focused and careful manner, free from the prejudices that might infect deliberations by a jury, that the determination should be made as a threshold matter.[21]

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[20] *See* United States v. Haro-Espinosa, 619 F.2d 789, 795 (9th Cir. 1979) (expert qualifications are preliminary question for the judge).

[21] *See In re* Agent Orange Product Liab. Litig., 611 F. Supp. 1267, 1269 (E.D.N.Y. 1985) ("The uncertainty of the evidence in [toxic tort] cases, dependent as it is on speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts and gatekeeping under Rules 403 and 703 by the court."), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

In rare cases, it may be difficult to distinguish truly revolutionary advances in science from aberrant hypotheses that will never be corroborated.[22] The best decision rule in such a situation may be to err on the side of caution and exclude the evidence. Although a favorable decision for a party who relies on dubious science does not result in an imprimatur of validity within the scientific community,[23] it can unwittingly inject bad science into broader decisions affecting society (for example, by encouraging meritless litigation against the producers of products that in fact are safe, or, even worse, by causing the abandonment of products that might prevent injuries). Subjecting uncorroborated hypotheses to heightened skepticism pending further testing and review is, thus, consistent with the aims of the law as well as those of science.

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[22] It is unlikely that a court will be faced with an expert proposing a true breakthrough and, in any event, "it is extremely unlikely that there will be any judges scientifically sophisticated enough to recognize such a genius, or his theories, before the scientific community gives its recognition." Loevinger, *Science and the Legal Rules of Evidence--A Review of Galileo's Revenge*, 32 JURIMETRICS J. 487, 495 (1992).

[23] *See, e.g.*, Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 744-45 (11th Cir.) (upholding verdict in favor of person who claimed that her birth defects had been caused by a spermicidal jelly used by her mother), *cert. denied*, 479 U.S. 950 (1986). Two physicians from the National Institute of Child Health and Human Development noted that the "decision took the medical community by surprise, because the overwhelming body of evidence indicates that spermicides are not teratogenic." Mills & Alexander, *Teratogens and Litogens*, 315 NEW ENGL. J. MED. 1234, 1235 (1986).

D. Threshold Determinations Concerning The Admissibility Of Scientific Evidence Are Consistent With The Federal Rules Of Evidence.

The approach to scientific expert testimony suggested by *amici* fits within the plain meaning of the Federal Rules of Evidence. Three rules determine what a court must consider in determining whether to admit such testimony:

> (1) Rule 702 sets forth the kinds of knowledge about which experts can testify, who qualifies as an expert, and how the testimony must relate to the facts of the case.
>
> (2) Rule 703 requires that the facts or data upon which an expert bases his or her opinions or inferences must be of a type reasonably relied upon for that purpose in the expert's field.
>
> (3) Rule 403, which applies to all evidence, allows a court to exclude otherwise admissible scientific evidence if its probative value is substantially outweighed by the danger of unfair prejudice or other countervailing factors.

Taken together, these rules provide judges with ample authority to screen and exclude expert testimony based on dubious science.

Under Rule 702, a party seeking to introduce scientific knowledge through a qualified expert must establish that the evidence is based on scientific principles. In applying this standard, the court must focus its inquiry on the putative

expert's reasoning.[24] Properly applied, Rule 702 authorizes scientifically qualified witnesses to testify, but their testimony must be founded on scientifically valid methodologies.

Rule 703 allows experts to base opinions or inferences on facts or data not admissible as evidence, but only if the facts or data are of a type reasonably relied upon within the expert's field. The plain language of the Rule makes clear that scientific standards apply to the factual basis for expert testimony, and that an expert's reliance on facts must be in accord with the practices of the field. Although it is more limited in scope than Rule 702, Rule 703 reflects the overall concern that scientific experts adhere to scientific standards when they testify.[25]

Rule 403 also emphasizes the need to scrutinize scientific evidence closely. The Rule provides that relevant

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[24] *See* Christophersen v. Allied Signal Corp., 939 F.2d 1106, 1115 (5th Cir. 1991) (per curiam) (expert must connect the facts to conclusion in a scientifically valid way), *cert. denied*, 112 S. Ct. 1280 (1992); Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 310 (5th Cir. 1989) ("courts must critically evaluate the reasoning process by which the experts connect data to their conclusions"), *cert. denied*, 494 U.S. 1046 (1990); Hull v. Merck & Co., 758 F.2d 1474, 1477 (11th Cir. 1985). *See also* Black, *supra* note 10.

[25] *See* Brown v. Parker-Hannifin Corp., 919 F.2d 308, 311 (5th Cir. 1990); Slaughter v. Southern Talc Co., 919 F.2d 304, 306-07 (5th Cir. 1990) (court should assess the reliability of the sources of an expert opinion); Head v. Lithonia Corp., 881 F.2d 941, 944 (10th Cir. 1989) (court must make preliminary determination whether the data underlying an expert's conclusion is reasonably relied upon by experts in the field).

and otherwise admissible evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.[26] For scientific evidence, the evaluation of probativeness necessarily involves the same kind of validity and reliability analysis that is required under Rules 702 and 703.[27] Consideration of the other factors enumerated in Rule 403 reinforces the basic theme: requiring the jury to listen to a battle of experts over the merits of an unreliable scientific procedure or theory can only create confusion by focusing the jury on a collateral issue at the expense of valuable time. If arguably invalid scientific evidence were to be admitted as a matter of course, the party opposing it would have to be allowed time to educate the jury about science and the deficiencies of the particular evidence in question, which is exactly the kind of misallocation of judicial resources that Rule 403 seeks to prevent.[28]

Close judicial scrutiny of the foundations for expert testimony is commended by the Federal Rules of Evidence,

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[26] *See* Turner v. Allstate Insur. Co., 902 F.2d 1208, 1214 (6th Cir. 1990) (upholding exclusion of survey because "the statistical data had a serious potential for confusing the jury and being misinterpreted").

[27] *See* Viterbo v. Dow Chemical Co., 826 F.2d 420, 422-24 (5th Cir. 1987) (upholding exclusion of expert testimony which lacked any reliable scientific foundation).

[28] *See In re* Agent Orange Product Liab. Litig., 611 F. Supp. 1223, 1256 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

which direct courts to control the admission of evidence to facilitate accurate fact-finding. To best accomplish this objective when addressing the admissibility of scientific evidence, courts should make full use of the scientific community's own standards and techniques for judging the validity and reliability of new hypotheses and research.

* * * *

The scientific community's well established criteria and institutional mechanisms for evaluating the validity of scientific assertions provide courts with clear and understandable guidance on how they can rationally and consistently evaluate scientific evidence. Courts should admit scientific evidence only if it conforms to scientific standards and is derived from methods that are generally accepted by the scientific community as valid and reliable. Such a test promotes sound judicial decisionmaking by providing workable means for screening and assessing the quality of scientific expert testimony in advance of trial.

CONCLUSION

For the foregoing reasons, *amici* urge this Court to uphold the broad authority of courts to exclude putatively scientific evidence that does not, according to the standards applied by the scientific community, have the earmarks of scientific reliability.

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